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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/720,934      | 01/02/2001  | Julie R. Korenberg   | 2320-1-001PCT/US    | 8413             |

7590

03/27/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/27/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/720,934

Applicant(s)

KORENBERG ET AL.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- a. Group I, claim(s) 1-31, and 51, drawn to a nucleic acid, oligonucleotide, vector, host vector system, pharmaceutical composition and a method of making a polypeptide.
- b. Group II, claim(s) 32-34 drawn to a polypeptide.
- c. Group III, claim(s) 35-36, drawn to an antibody.
- d. Group IV, claim(s) 37-39, drawn to a method of determining a mutation in the SH3D1A gene of a patient.
- e. Group V, claim(s) 40, drawn to a method of determining whether a subject has an megakaryocytic abnormality or disorder using an antibody.
- f. Group VI, claim(s) 41-44 and 50, drawn to a method of determining whether a subject has an megakaryocytic abnormality or disorder using a nucleic acid.
- g. Group VII, claim(s) 45 and 48, drawn to a method of suppressing cells and identifying an agent capable of suppressing cells.
- h. Group VIII, claim(s) 46 drawn to a method of screening for a somatic alteration in a SH3D1A gene by comparing DNA.
- i. Group IX, claim(s) 47, drawn to a method of screening for a somatic alteration in a SH3D1A gene by comparing polypeptides.
- j. Group X, claim(s) 48, drawn to a method of monitoring treatment by comparing nucleic acids at various stages.
- k. Group XI, claim(s) 52-56, drawn to a method of treatment with a nucleic acid.

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1. Group XII, claim(s) 457 drawn to a transgenic nonhuman mammal comprising the SH3D1A.

A. In the event applicant elects Group I, claims 1-14 and 25, applicant is required to elect a single species of tumor antigen peptide, comprising:

SEQ ID NO: 1-36 and 41-43

The species are patentably distinct based on structural and functional differences and mode of action.

2. The inventions have been found by the examiner to have no special technical feature that defined a contribution over the prior art because Chen, et al, (1997) teach gene maps of SH3D1A. Since the inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single inventive concept and lack unity of invention.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I is drawn to a nucleic acid of SH3D1A. The invention of Group II is drawn a polypeptide of SH3D1A. The invention of Group III is drawn to an antibody of SH3D1A. The invention of Group IV is to a method of determining a mutation in the SH3D1A gene of a patient. The invention of Group V is drawn to a method of determining whether a subject has an megakaryocytic abnormalilty or disorder in SH3D1A. The invention of Group VI is drawn to a method of determining whether a subject has an megakaryocytic abnormalilty or disorder SH3D1A using a nucleic acid. Group VII is drawn to a method of suppressing cells and identifying an agent capable of suppressing cells. Group VIII is drawn to a method of screening for a somatic alteration in a SH3D1A gene by comparing DNA. Group IX is drawn to a method of screening for a somatic alteration in a SH3D1A gene by comparing polypeptides. Group X is drawn to a method of monitoring treatment by comparing nucleic acids at various stages. Group XI is drawn to a method of treatment with a nucleic acid. Group XII is drawn to a transgenic nonhuman mammal comprising the SH3D1A.

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3. The Inventions of Groups I-III and XII (products) and IV-XI (methods) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of may be used for a number of different processes that are very much unrelated. For example, the peptide of Group I may be used to make an antibody, the antibody of Group III may be used for immunopurification, and the nucleic acid of Group I may be used to make a protein and not just in the methods of Groups IV-XI.

4. The products of Groups I-III and V are drawn to structurally and functionally different molecules with different immunological properties, each invention requires different reagents and steps to make and characterize it.

5. The methods of Groups IV-XI relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Natalie A. Davis, PhD

March 25, 2002

  
ANTHONY C.  
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